Tezspire (tezepelumab)

Disclaimer

Clinical guidelines are developed and adopted to establish evidence-based clinical criteria for utilization management decisions. Clinical guidelines are applicable according to policy and plan type. The Plan may delegate utilization management decisions of certain services to third parties who may develop and adopt their own clinical criteria.

Coverage of services is subject to the terms, conditions, and limitations of a member's policy, as well as applicable state and federal law. Clinical guidelines are also subject to in-force criteria such as the Centers for Medicare & Medicaid Services (CMS) national coverage determination (NCD) or local coverage determination (LCD) for Medicare Advantage plans. Please refer to the member's policy documents (e.g., Certificate/Evidence of Coverage, Schedule of Benefits, Plan Formulary) or contact the Plan to confirm coverage.

Tezspire (tezepelumab) 1
- Summary 1
- Definitions 3
  - Medical Necessity Criteria for Initial Clinical Review 4
    - General Medical Necessity Criteria 4
    - Initial Indication-Specific Criteria 4
      - Asthma, Severe 4
      - Chronic Rhinosinusitis with Nasal Polyps (CRSwNP) 5
  - Medical Necessity Criteria for Subsequent Clinical Review 5
    - Subsequent General Medical Necessity Criteria 6
    - Subsequent Indication-Specific Criteria 6
      - Asthma 6
      - Chronic Rhinosinusitis with Nasal Polyposis (CRSwNP) 6
  - Experimental or Investigational / Not Medically Necessary[s] 7
- References 7
- Clinical Guideline Revision / History Information 8

Summary

Asthma is a chronic respiratory disease that affects the airways, leading to recurrent episodes of wheezing, breathlessness, chest tightness, and coughing. The condition is caused by a combination of genetic and environmental factors, such as allergens, pollutants, and respiratory infections. Asthma is characterized by inflammation of the airways, which makes them hypersensitive and prone to constricting in response to various triggers. The inflammation is driven by immune cells, including eosinophils, mast

cells, and T lymphocytes, which release pro-inflammatory mediators, such as histamine, leukotrienes, and cytokines.

Severe asthma is a type of asthma that is difficult to control and is characterized by persistent and frequent symptoms, exacerbations, and airflow limitation, despite adherence to maximal optimized therapy. According to the Global Initiative for Asthma (GINA), severe asthma is a subset of a "difficult-to-treat" asthma, which is defined as asthma that is uncontrolled despite medium-or high-dose inhaled corticosteroid (ICS), with a second controlled (including long-acting beta-agonists (LABA) or with maintenance oral corticosteroid, or that requires high-dose treatment to maintain good symptom control and reduce risk of exacerbation. Severe asthma is specifically defined as asthma that is uncontrolled despite high-dose ICS/LABA treatment and management of contributory factors (e.g., inhaler technique, adherence, comorbidities), or that worsens when high-dose treatment is decreased. In addition, severe asthma may be associated with comorbidities such as obesity, sinusitis, and gastroesophageal reflux disease (GERD), and may require additional diagnostic tests, such as lung function tests, bronchial challenge tests, and imaging studies, to confirm the diagnosis and guide treatment.

The treatment of severe asthma requires a multi-faceted approach, including medication management, environmental control, and lifestyle modifications. The goal of treatment is to improve asthma control and reduce the risk of exacerbations. The following are some of the treatment options available for severe asthma:

- High-dose inhaled corticosteroids: These medications are the mainstay of treatment for asthma and are often used in combination with long-acting beta-agonists (LABAs). However, in severe asthma, higher doses may be required. As asthma progresses, individuals may require the addition of a long-acting muscarinic antagonist (LAMA) to the ICS-LABA therapy.
- Biologic medications: These medications are specifically designed to target specific immune pathways that contribute to asthma. Biologics are effective in reducing exacerbations and improving asthma control in severe asthma. Examples include Tezspire (tezepelumab), Xolair (omalizumab), Nucala (mepolizumab), Fasrena (benralizumab), and Dupixent (dupilumab).
- Oral corticosteroids: In severe asthma, oral corticosteroids may be necessary for short-term management of exacerbations. However, long-term use of oral corticosteroids can lead to serious side effects and should be avoided.
- Lifestyle modifications: Lifestyle modifications such as weight loss, exercise, and smoking cessation can help improve asthma control in people with severe asthma.

Tezspire (tezepelumab), a thymic stromal lymphopoietin (TSLP) blocker which may reduce the effect of the asthma inflammatory cascade, is indicated for the add-on maintenance treatment of adult and pediatrics aged 12 years and older with severe asthma. It is not indicated for the relief of acute bronchospasm or status asthmaticus. The recommended dosage of Tezspire (tezepelumab) is 210 mg administered subcutaneously once every 4 weeks. The pivotal trials, NAVIGATOR (12-80 years) and PATHWAY (18-75 years) were randomized placebo-controlled trials assessing the role of Tezpire (tezepelumab) in those with severe asthma receiving a medium-to-high dose ICS and at least one additional controlled medication, with or without oral glucocorticoids. Tezspire (tezepelumab) is unique in the lack of requirement of oral corticosteroid dependence, thus allowing those with severe asthma to receive additional therapy and avoid the potential risks of long-term corticosteroid use. In a pooled analysis of the NAVIGATOR and PATHWAY study, they found a significant reduction in the number of

annual asthma exacerbations, and exacerbation-related hospitalization and emergency department visits.

Tezspire (tezepelumab) was approved in 2025 for the indication of chronic rhinosinusitis with nasal polyps, a chronic condition affecting nasal sinuses and the lining of the nasal passage. Symptoms can include loss of smell, chronic congestion with nasal obstruction, nasal drainage and facial pressure. Management includes intranasal corticosteroids (e.g., fluticasone, mometasone), saline irrigation, systemic corticosteroids (e.g., prednisone), biologics (e.g., Dupixent [dupilumab], Xolair [omalizumab], Nucala (mepolizumab)) and nasal surgery.

Definitions

"Adjunctive therapy" refers to additional therapy, in addition to a primary treatment modality with a goal of enhancing the effectiveness of the primary treatment.

"Biomarker" is a substance found in the body that works as an indicator of exposure, effect, susceptibility, or clinical disease.

"Chronic rhinosinusitis with nasal polyposis (CRSwNP)" is chronic inflammation of the nose and paranasal sinuses with the presence of bilateral nasal polyps, often inadequately controlled with intranasal corticosteroids.

"Documentation" refers to written information, including but not limited to:

- Up-to-date chart notes, relevant test results, and/or relevant imaging reports to support diagnoses; or
- Prescription claims records, and/or prescription receipts to support prior trials of formulary alternatives.

"IgG2 lambda monoclonal antibody" is a laboratory-produced molecule that acts as a substitute antibody that can restore, enhance or mimic the immune system's attack on cells.

"Inhaled corticosteroids (ICS)" refer to inhaled steroid medications, aimed at reducing inflammation associated with respiratory diseases like asthma and chronic obstructive pulmonary disease (COPD).

"Leukotriene receptor antagonists (LTRA)" are oral medications which reduce inflammation associated with leukotrienes. Leukotrienes are released by the body and can cause coughing, excessive mucus production, inflammation of airways, tightness in the chest and wheezing or difficulty breathing.

"Long-Acting Beta-Agonist (LABA)" are long-acting inhalers which relax the smooth muscle of the airways, improving airflow in those with asthma and/or COPD.

"Long-Acting Muscarinic Antagonists (LAMA)" are inhaled medications which block the muscarinic receptor, responsible for constriction of the airways, thus reducing inflammation in the airways associated with asthma and/or COPD.

"Nasal polyps" are growths that form in the nose or the sinuses. They can be large or small, are usually found in both sides of the nose, and can make it hard to breathe through the nose.

"Phenotype" is a set of clinical characteristics, lung function and inflammation that is specific to a type of asthma as there are many different types of asthma.

"[s]" indicates state mandates may apply.

"Thymic stromal lymphopoietin (epithelial cytokine)" is a regulator of a type of immunity, which drives a broad range of allergic responses.

Medical Necessity Criteria for Initial Clinical Review

General Medical Necessity Criteria

The Plan considers Tezspire (tezepelumab) medically necessary when ALL of the following criteria are met:

1. Prescribed by or in consultation with a specialist experienced in the diagnosis and treatment of the relevant condition:
    a. Severe asthma - allergist/immunologist or pulmonologist*; or*
    b. Chronic rhinosinusitis with nasal polyps (CRSwNP) - allergist/immunologist or Ear, Nose and Throat (ENT) or otolaryngologist specialist*; AND*
2. The member is 12 years of age and older; *AND*
3. Tezspire (tezepelumab) is being prescribed at a dose and frequency that is within FDA approved labeling OR is supported by compendia or evidence-based published dosing guidelines for the requested indication.

    The requested medication is being used within the Plan's Quantity Limit of:
    - Tezspire (tezepelumab) 210 mg/1.91 ml (110 mg/1ml) solution in a single-dose pre-filled syringe: 1 syringe every 4 weeks
    - Tezspire (tezepelumab) 210 mg/1.91 ml (110 mg/1ml) solution in a single-dose pre-filled pen: 1 pen every 4 weeks
4. For all indications, the member cannot use the requested medication concomitantly with any other biologic drug or targeted synthetic drug for the same indication*; AND*
5. Documentation is provided showing the member meets ALL of the following indication-specific criteria below (see Initial Indication-Specific Criteria or Subsequent Indication-Specific Criteria):

Initial Indication-Specific Criteria

Asthma, Severe

The Plan considers Tezspire (tezepelumab) medically necessary when ALL the following criteria are met:

6. The member has a documented diagnosis of severe asthma*; AND*
7. The member has a history of ONE (1) or more of the following within the last 12 months:
    a. Two or more (≥2) exacerbations requiring oral/systemic corticosteroids treatment*; or*

b. One or more (≥1) exacerbation resulting in hospitalization or intensive care unit (ICU) admission*; AND*

8. The member has tried and failed, or is unable to use, ALL of the following at optimized[#] doses [s]:
    a. High-dose inhaled corticosteroids (ICS)*; and*
    b. Adjunctive therapy (in combination with inhaled corticosteroid), such as ONE (1) of the following:
        i. Long-Acting Beta-2 Agonists (LABA), such as formoterol or salmeterol*; or*
        ii. Leukotriene Receptor Antagonist (LTRA), such as montelukast (Singulair) or zafirlukast (Accolate)*; or*
        iii. Long-Acting Muscarinic Antagonists (LAMA), such as tiotropium; *or*
        iv. Extended-release theophylline*. AND*

    [#]*members should be receiving treatment with inhaled corticosteroid and additional controller (adjunctive therapy) for at least the previous 3 months.*
9. Tezspire (tezepelumab) will NOT be used as monotherapy.

<u>If the above prior authorization criteria are met, Tezspire (tezepelumab) will be approved for up to 6 months.</u>[s]

<u>Chronic Rhinosinusitis with Nasal Polyps (CRSwNP)</u>

The Plan considers <u>Tezspire (tezepelumab)</u> medically necessary when ALL the following criteria are met:

6. The member has a diagnosis of chronic rhinosinusitis with nasal polyps (CRSwNP)*; AND*
7. Documentation of bilateral nasal endoscopy or anterior rhinoscopy showing polyps reaching below the lower border of the middle turbinate or beyond in each nostril*; AND*
8. The member has nasal obstruction AND ONE (1) of the following additional symptoms:
    a. Rhinorrhea (anterior/posterior); *or*
    b. Reduction or loss of smell*; AND*
9. The member has CRSwNP despite ONE (1) of the following[s]:
    a. Prior sino-nasal surgery; *or*
    b. The member is unable to use or has tried and failed treatment with systemic corticosteroids within the last two years*; AND*
10. The member has bilateral nasal polyposis and chronic symptoms of sinusitis AND the member is unable to use or has tried and failed intranasal corticosteroid treatment for at least two (2) months[s]*; AND*
11. Tezspire (tezepelumab) will be used together with a daily intranasal corticosteroid as part of the member's treatment plan, unless the member is unable to use intranasal corticosteroid.

<u>If the above prior authorization criteria are met, Tezspire (tezepelumab) will be approved for up to 6 months.</u>[s]

Continued Care

Medical Necessity Criteria for Subsequent Clinical Review

All prior authorization renewals are subject to review. Reauthorization may be provided based on the diagnosis, response to therapy, and documented medical records and/or pharmacy claims.

Subsequent General Medical Necessity Criteria

The Plan considers Tezspire (tezepelumab) medically necessary when ALL of the following criteria are met:

1. Tezspire (tezepelumab) is being prescribed at a dose and frequency that is within FDA approved labeling OR is supported by compendia or evidence-based published dosing guidelines for the requested indication; *AND*
2. For all indications, the member cannot use the requested medication concomitantly with any other biologic drug or targeted synthetic drug for the same indication*; AND*
3. Documentation is provided showing the member meets ALL of the following indication-specific criteria below (see Initial Indication-Specific Criteria or Subsequent Indication-Specific Criteria):

Subsequent Indication-Specific Criteria

Asthma

The Plan considers Tezspire (tezepelumab) medically necessary when recent chart documentation (within the past 6 months) is provided showing ALL of the following criteria are met:

4. The member is 12 years of age or older; *AND*
5. The member's asthma has improved on Tezspire (tezepelumab) treatment based upon the prescriber's assessment as demonstrated by at least ONE (1) of the following:
    a. A reduction in the frequency and/or severity of symptoms and exacerbations*; or*
    b. A reduction in the daily maintenance oral corticosteroid dose*; AND*
6. Tezspire (tezepelumab) will NOT be used as monotherapy.

If the above reauthorization criteria are met, the requested product will be authorized for up to 12 months.[s]

Chronic Rhinosinusitis with Nasal Polyposis (CRSwNP)

The Plan considers Tezspire (tezepelumab) medically necessary when recent chart documentation (within the past 6 months) is provided showing ALL of the following criteria are met:

4. The member is 12 years of age or older; *AND*
5. The member's condition has improved on Tezspire (tezepelumab) treatment based upon the prescriber's assessment as demonstrated by symptomatic improvement of CRSwNP (e.g., improvement in nasal congestion, nasal polyp size, loss of smell, anterior or posterior rhinorrhea, sinonasal inflammation, hyposmia and/or facial pressure or pain or reduction in corticosteroid use)*; AND*
6. The member will continue consistent use of intranasal corticosteroids while on Tezspire (tezepelumab) therapy, unless the member is unable to use intranasal corticosteroid.

If the above reauthorization criteria are met, the requested product will be authorized for up to 12 months.[s]

Experimental or Investigational / Not Medically Necessary[s]

Tezspire (tezepelumab) for any other indication is considered not medically necessary by the Plan, as it is deemed to be experimental, investigational, unproven, or not medically necessary. Non-covered indications include, but are not limited to, the following:

- Atopic dermatitis (AD). Only one phase 2a study (n=113) has assessed the use of Tezspire (tezepelumab) for the treatment of AD. Participants were randomized to either Tezspire (tezepelumab) or placebo and a class 3 topical corticosteroid, and assessed for a primary outcome of 12-week response rate for ≥50% reduction in the Eczema Area and Severity Index (EASI50). There was no significant difference between Tezspire (tezepelumab) and placebo for the primary outcome: 64.7% versus 48.2% response rate in the Tezspire (tezepelumab) versus placebo group, respectively (p=0.091). At this time, there is not enough evidence to support the safety and efficacy of Tezspire (tezepelumab) for AD.
- Chronic obstructive pulmonary disease (COPD). Only one phase 2a study (n=333) has assessed the use of Tezspire (tezepelumab) for the treatment of COPD. Participants were randomized to either Tezspire (tezepelumab) or placebo, and assessed for a primary outcome of annualized rate of moderate or severe COPD exacerbations over 52 weeks. There was no significant difference between Tezspire (tezepelumab) and placebo for the primary outcome: 1.75 vs. 2.11 events per 52 weeks in the Tezspire tezepelumab) versus placebo group, respectively (rate ratio: 0.83 [90% CI 0.64-1.06], p=0.10). At this time, there is not enough evidence to support the safety and efficacy of Tezspire (tezepelumab) for COPD.
- Chronic spontaneous urticaria (CSU). Only one phase 2b study (n=183) has assessed the use of Tezspire (tezepelumab) for the treatment of CSU. Participants were randomized to either Tezspire (tezepelumab), placebo or Xolair (omalizumab) for 16 weeks. At 16-weeks, the primary endpoint of change from baseline in weekly Urticaria Activity Score (UAS7) were not met, Tezspire (tezepelumab) did not improve outcomes compared to placebo. They did, however, see a delayed response, with improvement in the UAS7 at 32 weeks - however they were not powered to see a difference at this timepoint. Further studies are needed to support the safety and efficacy of Tezspire (tezepelumab) for CSU.
- Eosinophilic esophagitis (EoE). There are no high quality studies to support the safety and efficacy of Tezspire (tezepelumab) for the treatment of EoE.

References

1. Agache I, Akdis CA, Akdis M, et al. EAACI Biologicals Guidelines-Recommendations for severe asthma. Allergy. 2021 Jan;76(1):14-44. doi: 10.1111/all.14425. Epub 2020 Aug 10.
2. AstraZeneca plc. (2020, December 22). Update on SOURCE Phase III trial for Tezepelumab in patients with severe, oral corticosteroid-dependent asthma. Available at: https://www.astrazeneca.com/media-centre/press-releases/2020/update-on-source-phase-iii-trial-for-tezepelumab-in-patients-with-severe-oral-corticosteroid-dependent-asthma.html. Last accessed December 27, 2021.

3. Cloutier MM, Dixon AE, Krishnan JA, et al. Managing asthma in adolescents and adults: 2020 asthma guideline update from the National Asthma Education and Prevention Program. JAMA. 2020;324(22): 2301-2317.
4. Corren J, AMbrose CS, Griffiths JM, et al. Efficacy of tezepelumab in severe allergic asthma: results from the phase 3 NAVIGATOR study. Clin Exp Allergy. 2023 Apr;53(4):417-428. doi:10.1111/cea.14256. Epub 2022 Dec 12.
5. Corren J, Menzies-Gow A, Chupp G, et al. Efficacy of tezepelumab in severe, uncontrolled asthma: a pooled analysis of the PATHWAY and NAVIGATOR clinical trials. Am J Respi Crit Care Med. 2023 Jul 1;208(1):13-24. doi:10.1164/rccm.202210-2005OC.
6. Corren J, Parnes JR, Wang L, et al. Tezepelumab in adults with uncontrolled asthma. N Engl J Med. 2017;377(10):936-946. doi:10.1056/NEJMoa1704064.
7. Department of Veterans Affairs/Department of Defense. VA/DoD Clinical Practice Guideline for the Primary Care Management of Asthma. Version 4.0-2025. Available at: https://www.healthquality.va.gov/guidelines/CD/asthma/Asthma-CPG_2025-Guideline_final_20250528.pdf. Accessed 13 February 2026.
8. Emson C, Diver S, Chachi L, et al. CASCADE: a phase 2, randomized, double-blind, placebo-controlled, parallel-group trial to evaluate the effect of tezepelumab on airway inflammation in patients with uncontrolled asthma. Respir Res. 2020 Oct 13;21(1):265. doi: 10.1186/s12931-020-01513-x.
9. Expert Panel Working Group of the National Heart, Lung, and Blood Institute. Guidelines 2020 focused updates for asthma management-summary reported. J Allergy Clin Immunol 2020;146(6):1217-1270.
10. Feleszko W, Caminati M, Gern JE, et al. Effect of tezepelumab on asthma exacerbations co-occurring with infection-attributed acute respiratory illnesses. Ann Allergy Asthma Immunol. 2026 Jan;136(1):61-65.e1. doi: 10.1016/j.anai.2025.09.015. Epub 2025 Oct 8.
11. Global Initiative for Asthma (GINA). Global strategy for asthma management and prevention. https://ginasthma.org/wp-content/uploads/2021/05/GINA-Main-Report-2021-V2-WMS.pdf. Updated 2021.
12. Global Initiative for Asthma (GINA). Global strategy for asthma management and prevention. Updated 2024. https://ginasthma.org/wp-content/uploads/2024/05/GINA-2024-Strategy-Report-24_05_22_WMS.pdf
13. Global Initiative for Asthma (GINA). Global strategy for asthma management and prevention. Updated 2025. https://ginasthma.org/wp-content/uploads/2025/11/GINA-2025-Update-25_11_08-WMS.pdf
14. Jackson DJ, Lugogo NL, Gurnell M, et al. Oral corticosteroid reduction and discontinuation in adults with corticosteroid-dependent, severe, uncontrolled asthma treated with tezepelumab (WAYFINDER): a multicentre, single-arm, phase 3b trial. Lancet Respir Med. 2026 Feb;14(2):129-140. doi: 10.1016/S2213-2600(25)00359-5. Epub 2025 Nov 26.
15. Jacobs JS, Han JK, Lee JK, et al. Effect of Tezepelumab on Sino-Nasal Outcome Test (SNOT)-22 Domain and Symptom-Specific Scores in Patients with Severe, Uncontrolled Asthma and a History of Chronic Rhinosinusitis with Nasal Polyps. Adv Ther. 2025 Jan;42(1):510-522. doi: 10.1007/s12325-024-03006-5. Epub 2024 Nov 8.
16. Lipworth BJ, Han JK, Desrosiers M, et al. Tezepelumab in Adults with Severe Chronic Rhinosinusitis with Nasal Polyps. N Engl J Med. 2025 Mar 27;392(12):1178-1188. doi: 10.1056/NEJMoa2414482. Epub 2025 Mar 1.
17. Lugogo NL, Akuthota P, Sumino K, et al. Effectiveness and Safety of Tezepelumab in a Diverse Population of US Patients with Severe Asthma: Initial Results of the PASSAGE Study. Adv Ther.

2025 Jul;42(7):3334-3353. doi: 10.1007/s12325-025-03231-6. Epub 2025 May 19. Erratum in: Adv Ther. 2025 Sep;42(9):4724-4725. doi: 10.1007/s12325-025-03316-2.
18. McLaren J, Chon Y, Gorski KS, et al. Tezepelumab for the treatment of chronic spontaneous urticaria: Results of the phase 2b INCEPTION study. J Allergy Clin Immunol. 2025 Jun;155(6):1945-1956. doi: 10.1016/j.jaci.2025.01.045. Epub 2025 Feb 14.
19. Menzies-Gow A, Ambrose CS, Colice G, et al. Effect of tezepelumab on lung function in patients with severe uncontrolled asthma in the phase 3 NAVIGATOR study. Adv Ther. 2023 Nov;40(11):4957-4971. doi:10.1007/s12325-023-02659-y. Epub 2023 Sep 19.
20. Menzies-Gow A, Bourdin A, Chugg G, et al. Effect of tezepelumab on healthcare utilization in patients with severe, uncontrolled asthma: the NAVIGATOR study. Ann Allergy Asthma Immunol. 2023 Sep; 131(3):343-348. E2. doi:10.1016/j.anai.2023.05.028. Epub 2023 May 30.
21. Menzies-Gow A, Colice G, Griffiths JM, et al. NAVIGATOR: a phase 3 multicentre, randomized, double-blind, placebo-controlled, parallel-group trial to evaluate the efficacy and safety of tezepelumab in adults and adolescents with severe, uncontrolled asthma. Respir Res. 2020;21(1):266. doi:10.1186/s12931-020-01526-6
22. Menzies-Gow A, Corren J, Bourdin A, et al. Tezepelumab in adults and adolescents with severe, uncontrolled asthma. N Engl J Med. 2021;384(19):1800-1809. doi:10.1056/NEJMoa2034975.
23. Menzies-Gow A, Ponnarambil S, Downie J, et al. DESTINATION: a phase 3, multicentre, randomized, double-blind, placebo-controlled, parallel-group trial to evaluate the long-term safety and tolerability of tezepelumab in adults and adolescents with severe, uncontrolled asthma. Respir Res. 2020 Oct 21;21(1):279. doi:10.1186/s12931-020-01541-7.
24. Menzies-Gow A, Wechsler ME, Brightling CE, et al. Long-term safety and efficacy of tezepelumab in people with severe, uncontrolled asthma (DESTINATION): a randomised, placebo-controlled extension study. Lancet Respir Med. 2023 May;11(5):425-438. doi:10.1016/S2213-2600(22)00492-1. Epub 2023 Jan 23.
25. National Institute of Health and Care Excellence. Asthma: diagnosis, monitoring,and chronic asthma management (BTS, NICE, SIGN). NG245. 27 Nov 2024. Available at: https://www.nice.org.uk/guidance/ng245/chapter/Recommendations. Accessed 13 Feb 2026.
26. Pavord ID, Hoyte FCL, Lindsley AW, et al. Tezepelumab reduces exacerbations across all seasons in patients with severe, uncontrolled asthma (NAVIGATOR). Ann Allergy Asthma Immunol. 2023 Nov;131(5):587-597.e3. doi:10.1016/j.anai.2023.08.015. Epub 2023 Aug 23.
27. Simpson EL, Parnes JR, She D, et al. Tezepelumab, an anti-thymic stromal lymphopoietin monoclonal antibody, in the treatment of moderate to severe atopic dermatitis: A randomized phase 2a clinical trial. J Am Acad Dermatol. 2019 Apr;80(4):1013-1021. doi: 10.1016/j.jaad.2018.11.059. Epub 2018 Dec 12.
28. Singh D, Brightling CE, Rabe KF, et al. Efficacy and safety of tezepelumab versus placebo in adults with moderate to very severe chronic obstructive pulmonary disease (COURSE): a randomised, placebo-controlled, phase 2a trial. Lancet Respir Med. 2025 Jan;13(1):47-58. doi: 10.1016/S2213-2600(24)00324-2. Epub 2024 Dec 6.
29. Tezspire (tezepelumab) [prescribing information]. Thousand Oaks, CA: Amgen, Inc; May 2023.
30. Wechsler ME, Brusselle G, Virchow JC, et al. Clinical response and on-treatment clinical remission with tezepelumab in a broad population of patients with severe uncontrolled asthma: results over 2 years from the NAVIGATOR and DESTINATION studies. Eur Respir J. 2024 Dec 5;64(6):2400316. doi:10.1183/13993003.00316-2024. Print 2024 Dec.
31. Wechsler ME, Menzies-Gow A, Christopher E Brightling CE, et al, SOURCE study group. Evaluation of the oral corticosteroid-sparing effect of tezepelumab in adults with oral corticosteroid-dependent asthma (SOURCE): a randomised, placebo-controlled, phase 3 study. Lancet Respir Med. 2022 Mar 29;S2213-2600(21)00537-3. Online ahead of print.

Clinical Guideline Revision / History Information

Original Date: 03/17/2022
Reviewed/Revised: 3/23/2023, 06/29/2023, 3/21/2024, 7/1/2025, 02/02/2026, 07/01/2026